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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,005	11/18/2005	David Neil Cooper	348-077	2635
1009	7590	10/26/2007		
KING & SCHICKLI, PLLC 247 NORTH BROADWAY LEXINGTON, KY 40507			EXAMINER MACFARLANE, STACEY NEE	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/535,005	Applicant(s) COOPER ET AL.	
	Examiner Stacey MacFarlane	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-150 is/are pending in the application.
- 4a) Of the above claim(s) 29-38 and 40-140 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39, 141-150 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 May 2005 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/16/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group 5, Claim 39, in the reply filed on September 14, 2007 is acknowledged. The traversal is on the ground(s) that there is improper finding of lack of unity of invention (page 25 of Reply filed September 14, 2007). This is not found persuasive because the invention of Group 5, directed to "an isolated polypeptide which is a variant of the growth hormone protein, GH, and which includes the substitution Ile179Met" (Claim 39), differs in scope from the invention of Group 14 directed to "an isolated growth hormone polypeptide or protein which contains a Ile179Met substitution" (Claim 49) and from the invention of Group 15 directed to "an isolated growth hormone polypeptide or protein which is characterized by possessing a reduced ability to activate the MAP kinase pathway" (Claim 54). One of ordinary skill in the art can envision embodiments of each that fall outside the requirements of the others. For example, the Takahashi et al. reference cited on page 4 of the Paper filed August 14, 2007 teaches an isolated growth hormone polypeptide that has reduced JAK2 tyrosine phosphorylation (Figure 6) and thus MAP kinase activity (as defined by the instant specification paragraph 0015). Since the prior art teaches the limitations of Group 15, unity between the traversed groups 5, 14, and 15 does not exist.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-28 have been cancelled and Claims 141-150 have been added in the amendment filed September 14, 2007.

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3. Claims 29-38 and 40-140 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on September 14, 2007.
4. Claims 39 and 141-150 are under examination in the instant Office Action.

Claim Objections

5. Claims 149 and 150 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 149 depends from claim 39, which is limited to a polypeptide while claim 149 encompasses a nucleic acid molecule. Claim 149 is improper because it can be infringed by the nucleic acid molecule of *GH1*, which does not infringe claim 39. Claim 150 is included in the objection because it depends from claim 149. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
7. Claims 39, 141-150 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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8. Claim 39 is vague and indefinite for reference to "Ile179Met". The exact amino acid positions and residues vary between species from which "the growth hormone protein" is isolated, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention absent a reference sequence.

9. The terms "reduced activity" and "a reduced ability" in claims 142 and 146 are relative terms that render the claim indefinite. The term "reduced" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

10. Claim 149 is vague and indefinite in its recitation of "a protein, i.e. a GH protein, including the substitution Ile179Met". By reciting "a GH protein" the claim reads upon wild-type protein but the subsequent inclusion of the substitution renders it no longer GH but a variant. Furthermore, Claim 149 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the steps by which the variant is made from the nucleic acid sequence of wild type *GH1*.

11. Claim 150 is vague and indefinite in its recitation of "a polypeptide or protein" produced by the method. One reasonably appreciates that the method would produce a plurality of polypeptides and it is unclear which one is claimed.

12. Claims 141, 143-145, and 147-148 are indefinite for depending from indefinite claims.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. Claims 39 and 141-150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham et al. US Patent 5534617, issued July 1996 and hereafter referred to as the '617 Patent.

Claims 39 and 141-150 are drawn to an isolated polypeptide which is a variant of the growth hormone protein, GH, and which includes the substitution Ile179Met, and a process for preparing said isolated polypeptide.

The '617 Patent teaches the production of random mutations at position 179 by methods of scanning isosteric substitutions. The method teaches the isosteric amino acid substitutions for an Isoleucine residue are Methionine, Leucine and Valine (Column 11, Table at line 40). The reference teaches culturing host cells comprising a vector (Column 12, line 26 through Column 13, line 34), recovery of variant proteins (Column

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20, lines 22-56) and formulation of pharmaceutical compositions thereof (Column 20, line 60 through Column 22, line 24). Specifically, the '617 teaches variants in which the Isoleucine at position 179 was changed to Asparagine, Threonine, Valine, Serine (Table 7) and Alanine (Table 2, column 29). The '617 Patent does not teach the specific substitution of Methionine at position 179 but explicitly identifies Methionine as an isosteric or sterically conserved amino acid substitution for Isoleucine. A skilled artisan would be able to use the substitution methodology as taught by the '671 Patent in combination with the isosteric amino acid substitutions as also taught within the reference to produce the isolated Ile179Met variant of the claims. One would be motivated to do so because the reference explicitly teaches that such substitution would "minimize the potential disruptive effects on conformation that some substitutions can cause" (Column 11, lines 35-37).

Double Patenting

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

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be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims 39 and 141-150 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4, 5, 8, 24 and 27-28 of copending Application No. 10/495,235. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn the isolated growth hormone variant which includes the substitution Ile179Met.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

18. Applicant is advised that should claim 39 be found allowable, claims 141-147 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof, because they do not alter the structure of the invention. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Conclusion

19. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacey MacFarlane whose telephone number is (571) 270-3057. The examiner can normally be reached on M,W and ALT. F 6 am to 3 pm, T & R 5:30 am - 4 pm..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stacey MacFarlane
Examiner
Art Unit 1649

SNM


OLGA N. CHERNYSHEV, PH.D.
PRIMARY EXAMINER